

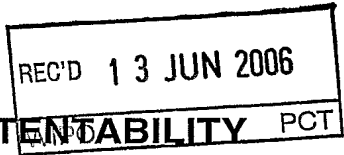
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P31986	FOR FURTHER ACTION		See Form PCT/PEA/416																								
International application No. PCT/US2005/008010	International filing date (day/month/year) 10.03.2005	Priority date (day/month/year) 10.03.2004																									
International Patent Classification (IPC) or national classification and IPC INV. A61F5/01																											
Applicant OMNI LIFE SCIENCE, INC. et al.																											
<ol style="list-style-type: none"> 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 5 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 13 sheets, as follows: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 																											
<ol style="list-style-type: none"> 4. This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 10%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> 				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 10.01.2006		Date of completion of this report 12.06.2006																									
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>		Authorized officer Josten, S Telephone No. +49 89 2399-2338																									



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2005/008010

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-19 as originally filed

Claims, Numbers

1-25 received on 23.05.2006 with letter of 19.05.2006

Drawings, Sheets

1/8-8/8 received on 23.06.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☒ the claims, Nos. 8
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2005/008010

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-25
	No: Claims	
Inventive step (IS)	Yes: Claims	1-25
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item I

Basis of the report

1. This IPER has been established as if the amendments to claim 8, i.e. the replacement of the wording "lower cuff" by the wording "resilient liner (46)" had not been made, since this amendment has no basis in the originally filed documents (Rule 70.2(c) PCT). As can be seen from the figures and the description the resilient liner 46 is formed by a plurality of discrete liner segments 49 and these liner segments are removably attached to either the upper cuff 22 or the lower cuff 25. However, there is no disclosure in the originally filed documents that the liner segments are removably attached to the resilient liner 46.

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

2. Reference is made to the following documents:

D1: US-A-4 938 207 (VARGO ET AL) 3 July 1990 (1990-07-03)
D2: DE 201 16 887 U1 (HEFELE, WILHELM JOSEPH) 28 February 2002 (2002-02-28)
D3: US 2003/187375 A1 (GAYLORD ERIC LEE) 2 October 2003 (2003-10-02)
D4: US-A-4 872 448 (JOHNSON, JR. ET AL) 10 October 1989 (1989-10-10)
D5: US-A-6 110 135 (MADOW ET AL) 29 August 2000 (2000-08-29)

3. The document **D1** is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references applying to this document):

A knee brace for a user comprising:

a rigid arm 400, 420 (see Figure 7) having a hinge assembly 330 near a midpoint thereof;

a semi-rigid cuff assembly 350, 360 connected to said rigid arm and adapted to fit

snugly about a leg of the user such that said hinge assembly is adjacent the user's knee;
at least one strap 22, 24 for securing said knee brace to the user's knee; and
a resilient liner having a plurality of discrete liner segments 50, 52, 54, 56, 58, 60, 62, 64, said resilient liner connected to an interior portion of said cuff assembly for providing a secure fit between said cuff assembly and the user's leg;
said at least one liner segment is adapted to be secured between at least one of an upper cuff and a lower cuff of the cuff assembly and the thigh portion and calf portion, respectively, of the user.

Independent claim 1 differs from the disclosure of **D1** in the feature that at least one of said plurality of discrete liner segments is removable.

One or more removable discrete liner segments 1, 1a, 2, 2a may be known from **D2** (see the "Haftstreifen (3a)" fixed to the support members (3) in order to allow fixation of the liner segments). However, the man skilled in the art would not introduce this feature known from **D2** into the knee brace known from **D1** since such a combination would destroy the functionality of **D1**'s knee brace.

Consequently, the subject-matter of claim 1 meets the requirements of novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

4. Claims 2 to 25 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

5. The independent claim should have been properly cast in the two-part form, with those features which in combination are known from **D1** being placed in the preamble (Rule 6.3(b) PCT). Said two-part form would not render the claim less intelligible as can be seen from the above paragraph 3.

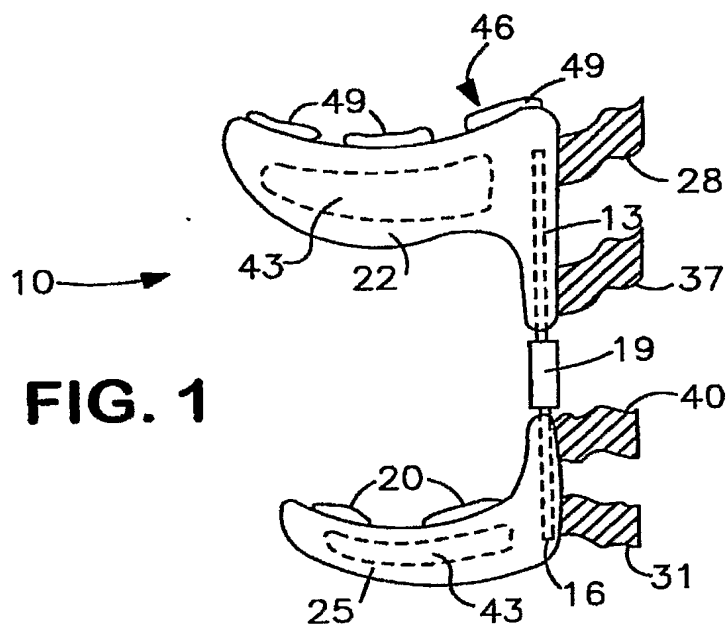


FIG. 1

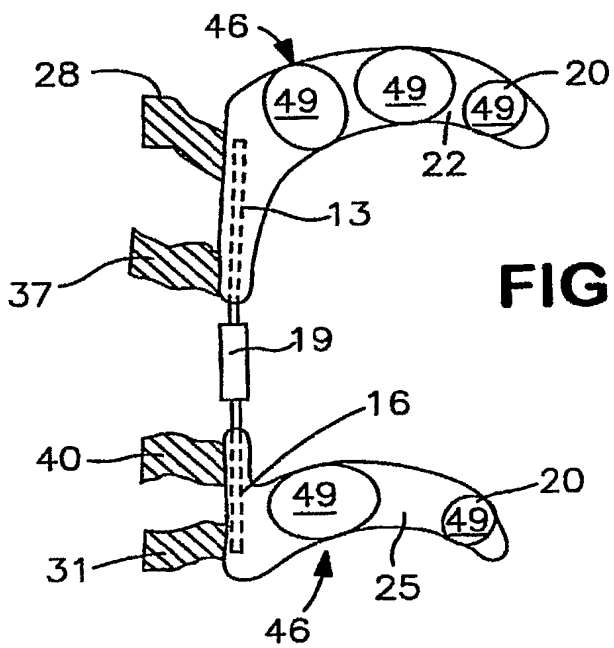


FIG. 2

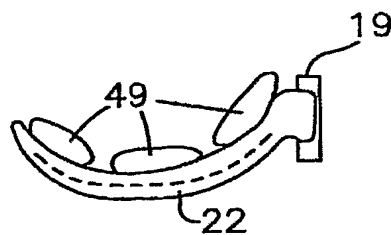


FIG. 3

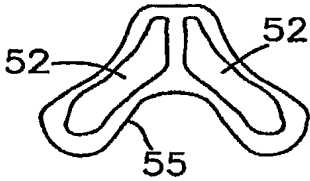


FIG. 4A

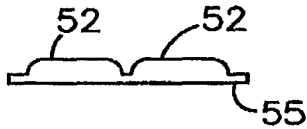


FIG. 4B



FIG. 5A

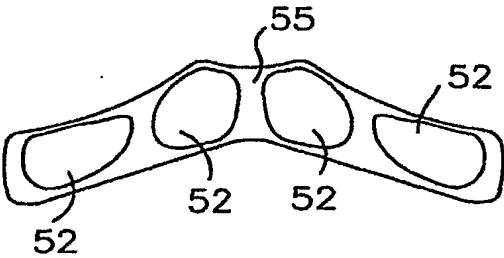


FIG. 5B

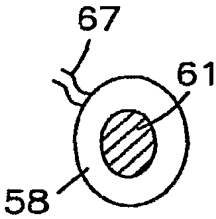


FIG. 6A

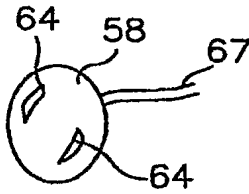


FIG. 6B

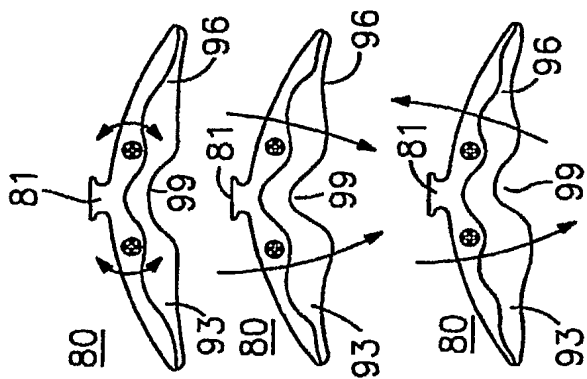


FIG. 11

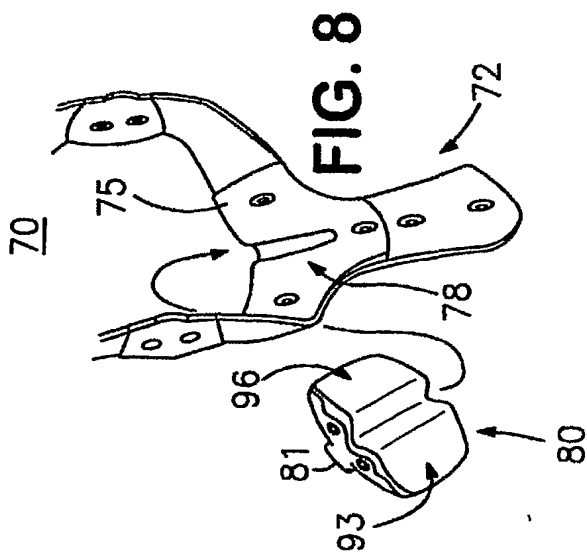


FIG. 8

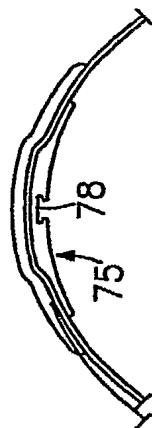


FIG. 9

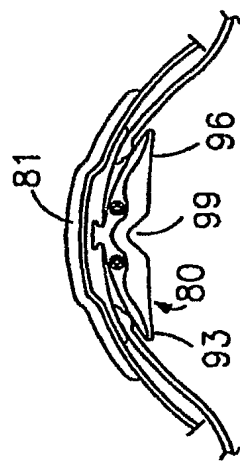


FIG. 10

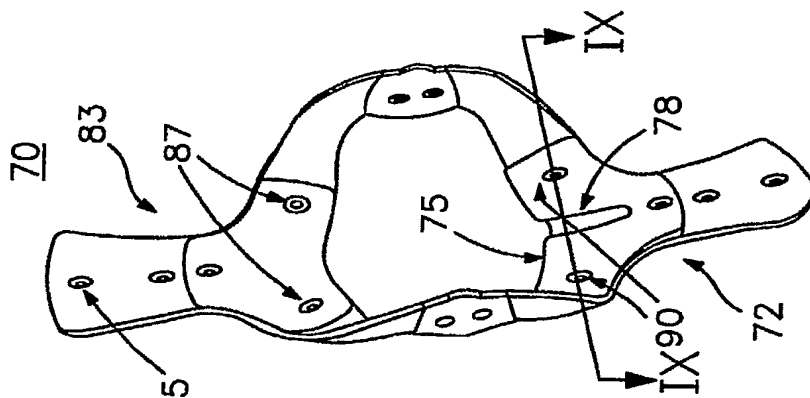
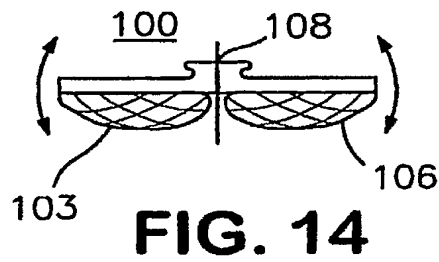
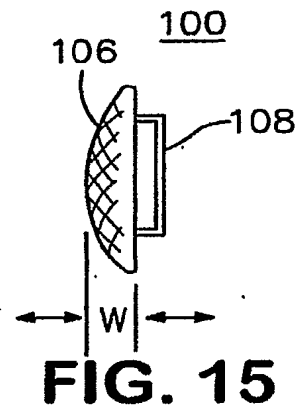
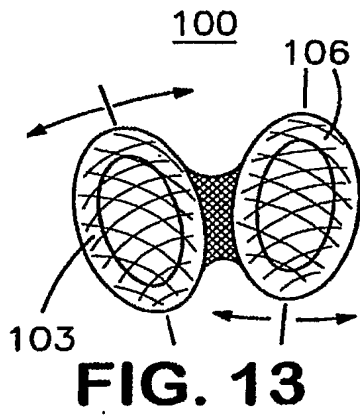
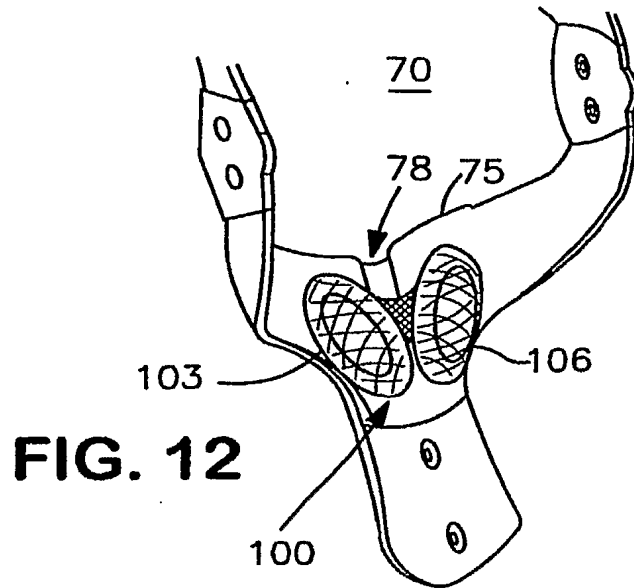


FIG. 7



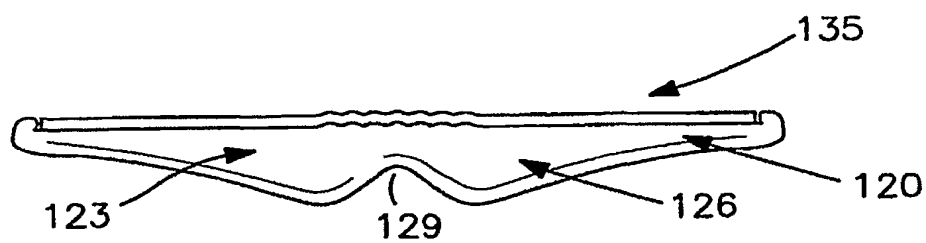


FIG. 17

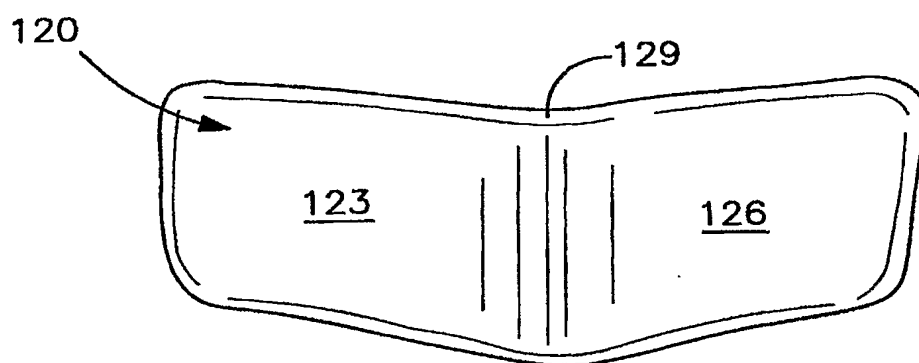


FIG. 16

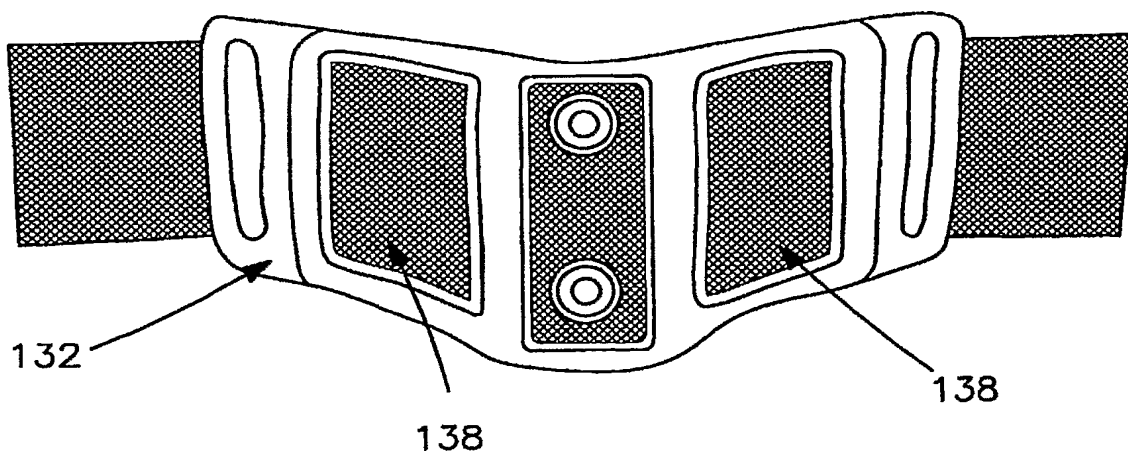


FIG. 18

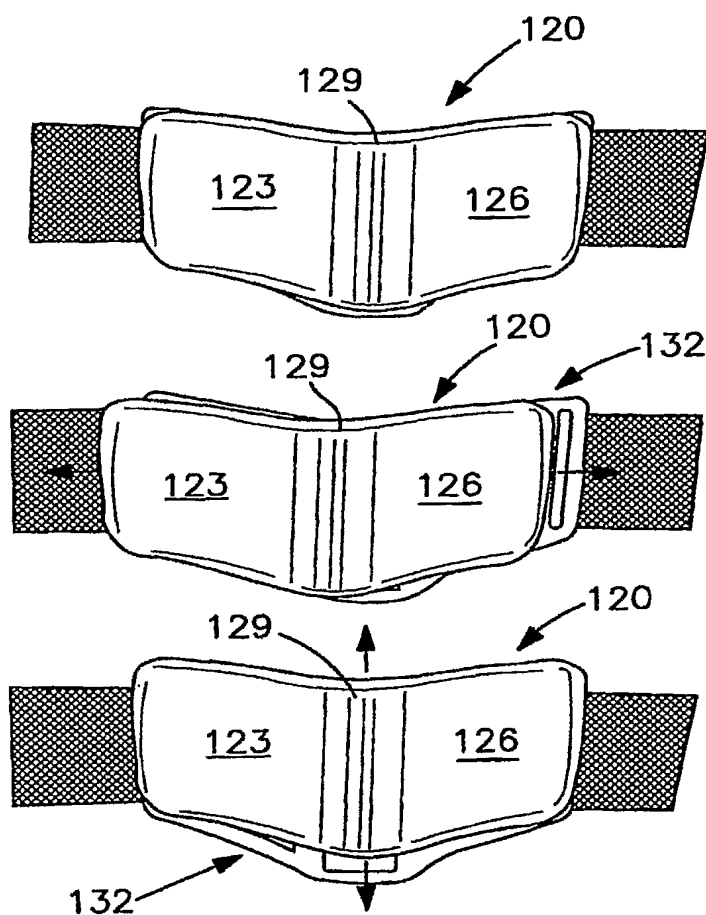


FIG. 19

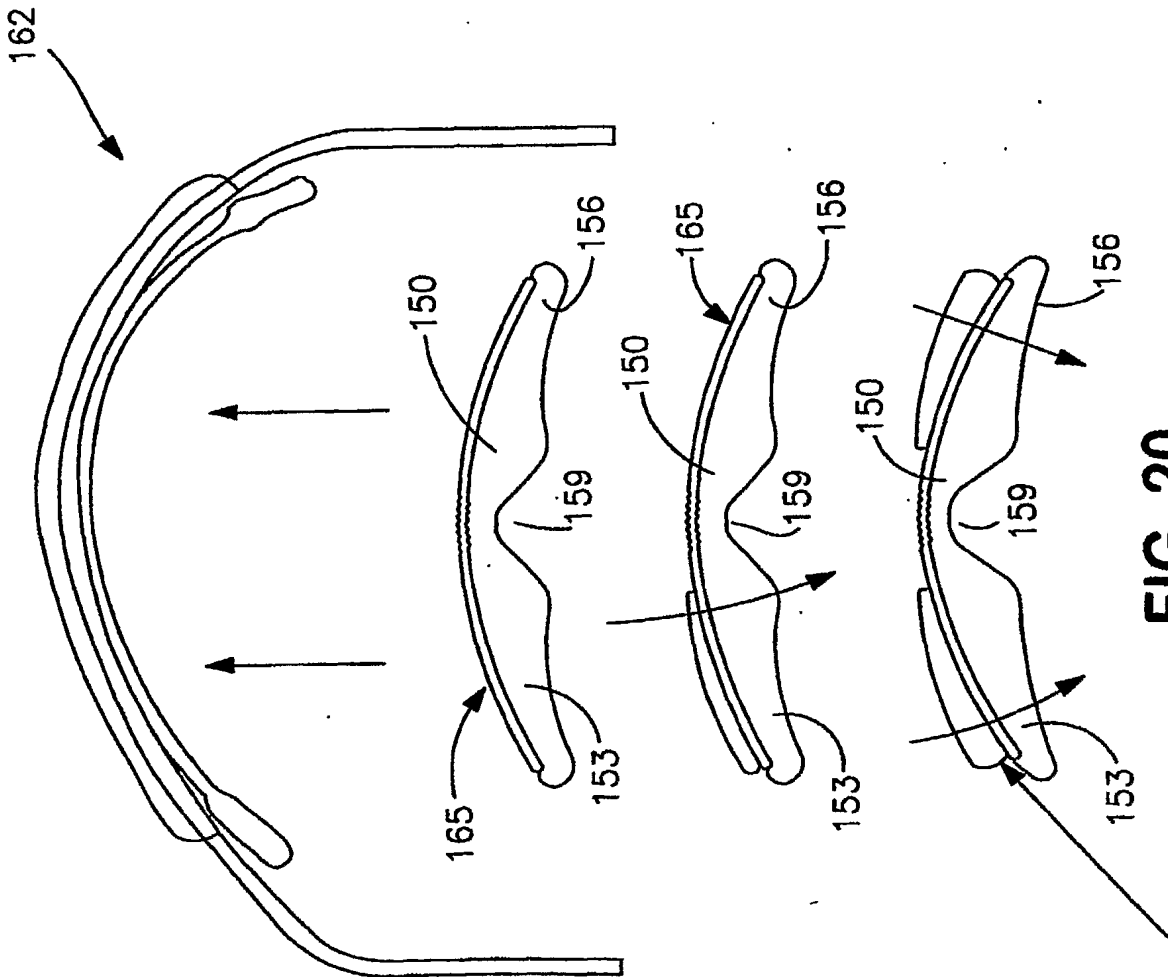


FIG. 20

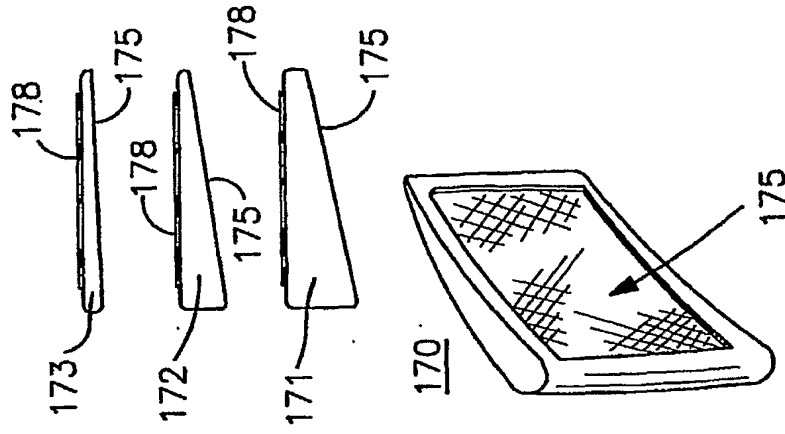
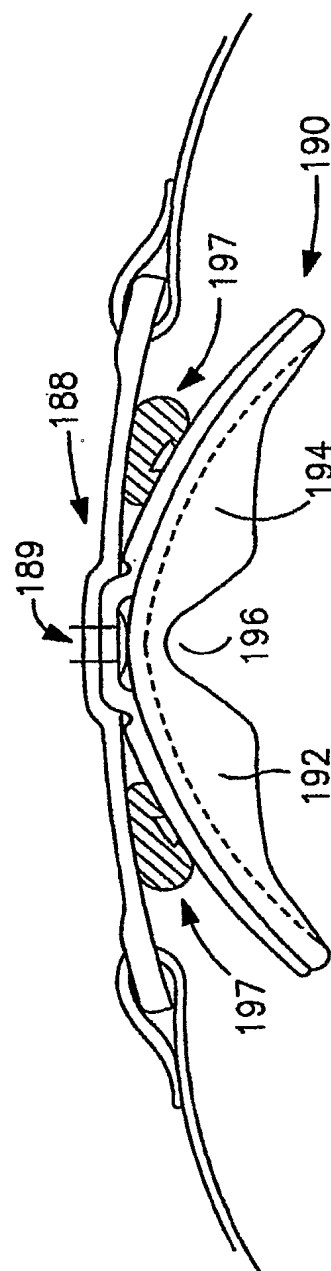
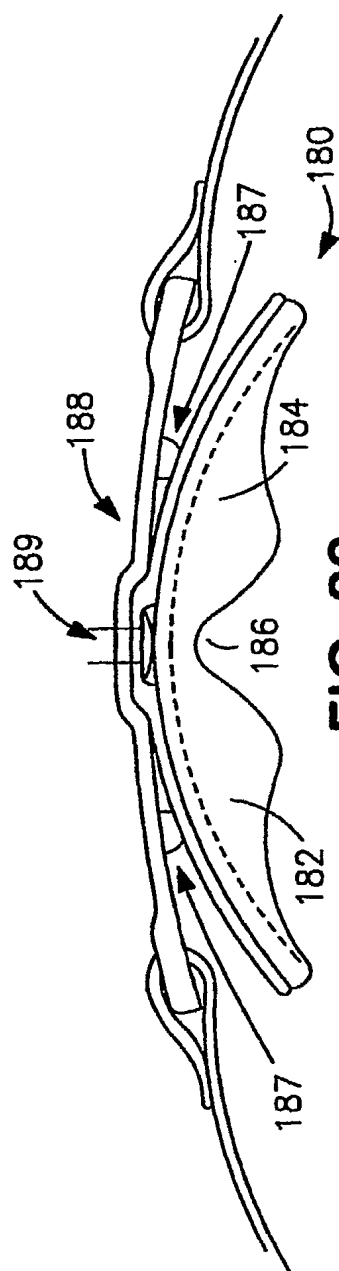


FIG. 21



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Claims

What is claimed is:

1. A knee brace (10) for a user comprising:
5 a rigid arm (13) having a hinge assembly (19) near a midpoint thereof;
a semi-rigid cuff assembly (22, 25) connected to said rigid arm (13) and adapted to fit snugly about a leg of the user such that said hinge assembly (19) is adjacent
10 the user's knee;
at least one strap (28) for securing said knee brace (10) to the user's knee; and
a resilient liner (46) having a plurality of discrete liner segments (49), said resilient liner (46)
15 connected to an interior portion of said cuff assembly (22, 25) for providing a secure fit between said cuff assembly (22, 25) and the user's leg;
wherein at least one of said plurality of discrete liner segments (49) is removable, and said at least one
20 removable liner segment (49) is adapted to be secured between at least one of an upper cuff (22) and a lower cuff (25) of the cuff assembly (22, 25) and the thigh portion and calf portion, respectively, of the user.
- 25 2. The knee brace (10) of claim 1, wherein said semi-rigid cuff assembly (22, 25) is further comprised of a thermoplastic material and a deformable metallic material such that said semi-rigid cuff assembly (22, 25) is generally conformable to the user's leg.
- 30 3. The knee brace (10) of claim 1, wherein said upper cuff (22) has a first strap (28) for securing said upper cuff (22) to a thigh portion of the user, and said

lower cuff (25) has a second strap (31) for securing said lower cuff (25) adjacent to a calf portion of the user.

- 5 4. The knee brace (10) of claim 3, wherein said at least one removable liner segment (49) conforms to the shape of at least one of the user's thigh portion and calf portion as the knee brace (10) is secured to the user by said first and second straps (28, 31).
- 10 5. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) further comprises a micro-porous waterproof cover material contacting the body portion of the user.
- 15 6. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) further comprises an electrode portion (58) operably connected to a source of electrical power such that electrical
- 20 stimulation is provided to the user's knee.
- 25 7. The knee brace (10) of claim 1, wherein at least one removable liner segment (49) is attached to one of said upper and lower cuffs (22, 25) via a hook and loop fastener system.
- 30 8. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) is removably attached to said resilient liner (46).
9. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) has an adjustable shape.

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10. The knee brace (10) of claim 9, wherein said at least one discrete liner segment (49) having an adjustable shape further comprises a pair of adjustable segment portions.

11. The knee brace (10) of claim 10, wherein each of said pair of adjustable segment portions is individually adjustable.

12. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) has an adjustable size.

13. The knee brace (10) of claim 12, wherein at least one of said plurality of discrete liner segments (49) is inflatable or deflatable to provide said adjustable size.

14. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) further comprises an electrode portion (58) operably connected to a source of electrical power to impart therapeutic stimulation to an associated body portion of the user.

15. The knee brace (10) of claim 1, wherein:
said upper cuff (22) is hinged to said lower cuff (25),
said upper cuff (22) being adapted to be secured to
adjacent a thigh of the user, and said lower cuff (25)
being adapted to be secured adjacent to a corresponding
calf of the user;
said hinge assembly (19) is located proximate the knee
joint of the user; and

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said plurality of discrete liner segments (49) is adapted to be secured between each of said upper and lower cuffs (22, 25) and the thigh and calf, respectively, of the user.

5

16. The knee brace (10) of claim 15, wherein said plurality of discrete liner segments (49) conforms to the shape of the user's thigh and calf as the knee brace (10) is secured to the user.

10

17. The knee brace (10) of claim 1, wherein:
said lower cuff (25) includes a back plate (188); and
at least one of said plurality of discrete liner segments (49) is attached to said back plate (188).

15

18. The knee brace (10) of claim 17, wherein at least one of said plurality of discrete liner segments (49) attached to said back plate (188) has an adjustable shape.

20

19. The knee brace (10) of claim 18, wherein said at least one of said plurality of discrete liner segments (49) having an adjustable shape further comprises a pair of adjustable segment portions (182, 184).

25

20. The knee brace (10) of claim 19, wherein each of said pair of adjustable segment portions (182, 184) is individually adjustable.

30

21. The knee brace (10) of claim 20, wherein said pair of adjustable segment portions (182, 184) comprises a pair of cam portions defining a tibial crest groove (186) therebetween, said pair of cam portions being

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individually adjustable on either side of said tibial crest groove (186) to at least one of conform to a particular shape of a user's tibia and maintain the tibia in a desired position.

5

22. The knee brace (10) of claim 1, wherein at least one of said plurality of discrete liner segments (49) has at least one of an adjustable shape and an adjustable size.

10

23. The knee brace (10) of claim 22, wherein said at least one of said plurality of discrete liner segments (49) further comprises a pair of segment portions, at least one of said pair being movable to provide said adjustable shape.

15

24. The knee brace (10) of claim 22, wherein said at least one of said plurality of discrete liner segments (49) is inflatable or deflatable to provide said adjustable size.

20

25. The knee brace (10) of claim 1, wherein said at least one removable liner segment (49) is removably attached to said lower cuff (25) by a hook and loop fastener system.

25